



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,036	08/08/2000	CHENGCAI CHU	PPD50288UST	2299

7590

04/09/2002

Hale and Dorr LLP
60 State Street
Boston, MA 02109

EXAMINER

KALLIS, RUSSELL

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 04/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/581,036

Applicant(s)

CHU ET AL.

Examiner

Russell Kallis

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Claim 2 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No 9. Claim 5 contains a Markush group after Applicant has elected invertase from that group. Claims should be amended to delete nonelected subject matter.

Claim Objections

1. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. The increase in fixed carbon is a natural consequence of transforming with the DNA construct. Hence, Claim 2 fails to further limit claim 1. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

2. Claim 1, 2, and 4-16 is objected to because of the following informalities:

At Claim 1 the spelling of "operable" in lines 3 and 4 should be --operably--.

At Claims 2, 4-16, "A method" should be --The method-- because they depend from Claim 1.

At Claim 10, the spelling of "aclR" in line 1 should be spelled --alcR--.

At Claim 12, the spelling of "promote" in line 2 should be --promoter--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1638

7. Claims 1-2 and 4-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At Claim 1, it is unclear what is encompassed by “controllable promoter” and “external chemical inducer”.

At Claim 2, the preamble contains a limitation “by selectively increasing the importation of fixed carbon into photosynthetically inactive sink tissue” to which it refers. Claim limitations are to be recited in the body of the claim. The claim should read as follows:

--A method of increasing the yield of a plant according to claim 1 whereby the transportation of fixed carbon from photosynthetically active source tissue to photosynthetically inactive tissue of said plant is selectively increased--.

At Claim 4, the use of “include” and “such as” renders the claim indefinite because it is unclear what else is encompassed.

At Claim 5, the use of “include” renders the claim indefinite because it is unclear what else is encompassed.

At Claim 7, “comprises” should be --is--.

At Claims 7, 9, 12, and 13, the use of “system” is unclear and renders the claim indefinite.

At Claims 9 and 13, the promoter is “alcA” not “the alcA/alcR promoter system”.

Claim 10 is improperly dependent on claim 9. It is unclear how the DNA encoding the alcR protein is related to the “DNA sequences” and “controllable promoter” of claim 1.

At claims 11-12, it is unclear what is encompassed by “controllable promoter”.

Art Unit: 1638

Claim 14 is improperly dependent on claim 13. It is unclear how the DNA encoding the alcR protein is related to the "DNA sequences" and "controllable promoter" of claim 11.

At Claim 16, the limitation "said plants" in line 2, lacks proper antecedent basis.

At Claim 16, both plant tissue and progeny of said plants are claimed. Applicant can't claim both plant tissue and progeny of said plants in the same claim.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-2 and 4-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of increasing the yield of a potato plant comprising transforming a potato plant with a DNA construct comprising the tuber specific patatin promoter operably linked to the alcR gene controlling the ethanol inducible alcA promoter operably linked to an invertase gene, does not reasonably provide enablement for a method of increasing the yield of any plant transformed with any DNA construct comprising one or more DNA sequences encoding a protein involved in sucrose sensing, transport, metabolism and/or uptake operably linked to any controllable promoter region controlled by an external chemical inducer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant claims a method of increasing the yield of a plant transformed with a DNA construct comprising one or more DNA sequences encoding a protein involved in sucrose sensing, transport, metabolism and/or uptake operably linked to a controllable promoter region

and transcription terminator, controlling the level, time, and spatial location of expression from the controllable promoter region by application of an external chemical inducer.

Applicant teaches a method of increasing the yield of a potato plant comprising transforming a potato plant with a DNA construct comprising the tuber specific patatin promoter operably linked to the alcR gene controlling the ethanol inducible alcA promoter operably linked to an invertase gene (specification page 18, lines 15-31).

Applicant does not teach tissue specific and ethanol inducible invertase expression, other than with the patatin promoter in potato tubers, using any of the tissue or organ specific promoters listed in the specification (page 4, lines 23-31, page 5, lines 1-6) in any other plant species and tissue type or organ thereof. Also, Applicant does not teach other controllable promoters than the alcA promoter, and other chemical inducers than ethanol.

Elevated invertase activity in experiments with transformed potato expressing yeast derived invertase in the cytosol, vacuole, or apoplast of potato leaves showed a decrease in photosynthesis as measured by a reduction in both Rubisco activation state and rate of CO₂ assimilation and an increase in solute accumulation in leaves in Bussis *et al.*, *Planta* 202:126-136, 1997 (Page 1, Abstract). Similar results were described in Sonnewald *et al.*, *Plant J.*, 1:95-106, 1991, where the activation state of Rubisco was down regulated in the leaves of tobacco plants transformed with invertase directed to either the apoplast, vacuole, or cytosol (page 1, Abstract). The down regulation of the activation state of Rubisco and the reduced rate of CO₂ assimilation, associated with the increased invertase activity, integrated over time will result in a loss of yield.

Since the promoters listed in the specification, other than patatin, are not specific to tubers, but encompass different tissue types or organs, such as seeds and leaves, it is unlikely that invertase expression in these tissues or organs would alone, to the extent provided by the construct, yield the same result shown in the patatin example.

Clearly not all tissue specific or organ specific promoters expressing invertase will enhance the yield of a plant when expressed in seed or forage tissue, because the changes introduced by the invertase activity itself have an unpredictable effect upon the physiology of the specific plant tissue or organ that can impact plant yield. One of skill in the art would be required to screen through a myriad of tissue and organ specific promoter-invertase DNA constructs and plants transformed therewith, to identify those plants with increased yield.

Switch promoter systems encompass different means of chemical induction for controlling the timing of gene expression. Applicant claims controllable and inducible promoter regions for the purpose of increasing yield, but does not teach the use of any controllable promoter system other than the ethanol inducible *alcA/alcR* system and any chemical inducer other than ethanol. In the absence of such guidance, undue experimentation would be required to identify other controllable promoters/chemical inducers that could be substituted for the *alcA* promoter/ethanol as disclosed. Also, since inducible promoter systems are sensitive to the concentration of chemical inducer, one of skill in the art would be required to determine both the precise timing and concentration of the chemical quantity to be applied for induction of gene expression sufficient to increase yield in sink tissue. Therefore, undue experimentation would be required.

Art Unit: 1638

Furthermore, it is noted that Applicant teaches a DNA construct comprising the alcA promoter (controllable promoter) operably linked to an invertase coding DNA and the patatin promoter operably linked to the alcR coding DNA. The encoded alcR protein is required for induction of the alcA promoter. Hence, the invention is only enabled when the DNA construct comprises the alcR coding DNA and the claims should be amended to reflect this.

Given the lack of guidance, the limited working examples in the specification, the breadth of the claims, and the unpredictability in the art, undue trial and error would be needed to practice the invention as claimed. Therefore, the invention is not enabled.

Claim Rejections - 35 USC § 101

10. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claim 16 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 16 is drawn to the progeny of the transformed plant. Due to Mendelian inheritance of genes, a single gene introduced into a parent plant would only be transferred at most to half the male gametes and half the female gametes. This translates into only two thirds of the progeny having at least a single copy of the transgene and one quarter of the progeny would not carry a copy of the transgene. Since the claim encompasses progeny that lack the transgene, the claim encompasses plants that are indistinguishable from plants that would occur in nature. See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948), and *In re Bergy, Coats, and Malik* 195 USPQ 344, (CCPA)

Art Unit: 1638

1977. Amendment of the claims to recite that the progeny comprise the construct that was introduced into the parent plant would overcome the rejection.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1-2 and 4-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Willmitzer *et al.* (U.S. Pat 5,436,394) in view of Caddick *et al.* (WO 93/21334).

The claims are drawn to a method of increasing the yield of a plant transformed with a DNA construct comprising one or more DNA sequences encoding a protein involved in sucrose sensing, transport, metabolism and/or uptake operably linked to a controllable promoter region and transcription terminator, controlling the level, time, and spatial location of expression from the controllable promoter region by application of an external chemical inducer.

Willmitzer teaches a method for production of transgenic potato plants, characterized by an increased yield, comprising transforming potato plants with an expression cassette having the class I patatin promoter operably linked to a DNA sequence expressing an invertase, containing the coding sequence for a functional protein inhibitor II signal peptide signal sequence, and regenerating a transformed potato plant (column 15 claims 5 and 8). Willmitzer differs from the immediate application in that he does not teach controlling the level, time, and spatial location of expression from a controllable promoter region by application of an external chemical inducer.

Caddick teaches the limitation of using a first promoter operatively linked to the alcA gene controlling the ethanol inducible alcR promoter driving the expression of a gene (Page 1, Abstract).

It would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Willmitzer, which is to substitute the alcA/alcR inducible promoter system of Caddick for the patatin promoter to further refine the control of timing of invertase gene expression in tubers to optimize yield. Caddick provides motivation by teaching transformation and stable incorporation into any plant genome (potato for example, listed on page 12 of the specification, lines 22-28) of the combination of a first promoter (e.g. patatin) operatively linked to the alcA gene and the alcR promoter operably linked to a functional protein (e.g. invertase). Therefore, the references as combined render obvious the claimed invention and thereby anticipate the instantly claimed invention.

14. All claims are rejected.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding, or if the examiner cannot be reached as indicated above, should be directed to the legal analyst, Kim Davis, whose telephone number is (703) 308-0009.

Application/Control Number: 09/581,036

Art Unit: 1638

Page 10

Russell Kallis Ph.D.

April 8, 2002

A handwritten signature in black ink, appearing to read "Amy Nelson". The signature is fluid and cursive, with the first name "Amy" and last name "Nelson" clearly distinguishable.

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600